

PATENT
454312-3140**REMARKS**

Reconsideration and withdrawal of the rejections of the application are respectfully requested in view of the amendments and remarks herewith, which place the application into condition for allowance.

Changes to the specification are intended to correct inadvertent errors. No new matter is added. Attached hereto is a marked up version of the changes made to the specification by this amendment. The attachment is captioned "Version With Markings to Show Changes Made."

I. Status of Claims and Formal Matters

Claim 1 has been amended; claims 1-3 are pending and under examination. The application now claims priority from U.S. application Serial No. 08/529,055, filed September 15, 1995, now abandoned. No new matter is added by these amendments. A new Declaration and Power of Attorney will be filed in due course.

It is submitted that the claims, herewith and as originally presented, are patentably distinct over the prior art cited by the Examiner, and that these claims were in full compliance with the requirements of 35 U.S.C. §112. The amendments of and additions to the claims, as presented herein, are not made for purposes of patentability within the meaning of 35 U.S.C. §§§§ 101, 102, 103 or 112. Rather, these amendments and additions are made simply for clarification and to round out the scope of protection to which Applicants are entitled. Support is found throughout the specification and from the pending claims.

With respect to the biological materials deposited with the ATCC, the undersigned states that he is an attorney of record, that the biological materials identified as deposited in the application were deposited under the terms of the Budapest Treaty with the American Type Culture Collection (ATCC), 12301 Parklawn Drive, Rockville, Maryland, 20852, USA, and:

- (a) during the pendency of this application, access to each of the Deposits will be afforded to the Commissioner upon request;
- (b) all restrictions upon availability of the each of the Deposits to the public will be irrevocably removed upon granting of the patent;
- (c) each of the Deposits will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer;

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- (d) a test of the viability of the biological material at the time of each of the Deposits was made; and
- (e) each of the Deposits will be replaced if it should ever become inviable.

It is thus believed that the Deposits, the claims, and the application conform with 35 U.S.C. §112.

II. The Rejection Under 35 USC §112, Second Paragraph Is Overcome

Claims 1-3 stand rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite. The use of an alternative expression, "and/or" in Claim 1, has been changed to "or". In addition, *Markush* language has been added to Claim 3. It is believed that these amendments obviate the rejection. Consequently, the Section 112, second paragraph, rejection should be reconsidered and withdrawn; and, such relief is respectfully requested.

III. The Rejection Under 35 USC 102 Is Overcome

Claims 1-3 stand rejected under 35 U.S.C. §102(a or b) as allegedly being anticipated by Brooks-Walter (ASM 1997 abstract), Briles *et al.* (1997 Microbial Drug Resistance; review presented in 1996) or Swiatlo *et al.* (1997).

It is respectfully pointed out that the documents cited in the Office Action do not constitute proper art. To wit, each of these documents has a date subsequent to the 1995 priority date of the instant application; and, each of the documents is not by "another" as to the present inventors. Consequently, the Section 102(a or b) rejection must fall. Furthermore, Applicants antedate at least as much as is shown by the references and therefore overcome them. *See In re Stempel*, 113, U.S.P.Q. 77, 81 (C.C.P.A. 1957). ("[A]ll the Applicant can be required to show is priority with respect to so much of the claimed invention as references happen to show. When he has done that, he has disposed of the reference.").

Even assuming, *arguendo*, that these documents are appropriately cited, they still do not anticipate the instant invention; therefore, this rejection is respectfully traversed.

The instant invention relates to epitopic regions of Pneumococcal Surface Protein C or "PspC". In particular, the instant invention relates to an isolated or purified polypeptide comprising a fragment or portion of PspC, such as an epitopic region of PspC or at least one epitope of PspC.

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The Office Action states that "the specification defines the epitope or epitopic region of PspC to be the proline rich region or the alpha helical region". Office Action at 3. In actuality, the specification, at pages 7 and 8, *inter alia* defines the epitope or epitopic regions of PspC far more broadly than stated in the Office Action, e.g., as recited in Claim 3. The Examiner is respectfully invited to review the specification, especially at pages 7 and 8.

It is respectfully pointed out that a two-prong inquiry must be satisfied in order for a Section 102 rejection to stand. First, the prior art reference must contain all of the elements of the claimed invention. See *Lewmar Marine Inc. v. Barient Inc.*, 3 U.S.P.Q.2d 1766 (Fed. Cir. 1987). Second, the prior art must contain an enabling disclosure. See *Chester v. Miller*, 15 U.S.P.Q.2d 1333, 1336 (Fed. Cir. 1990). A reference contains an enabling disclosure if a person of ordinary skill in the art could have combined the description of the invention in the prior art reference with his own knowledge of the art to have placed himself in possession of the invention. See *In re Donohue*, 226, U.S.P.Q. 619, 621 (Fed. Cir. 1985).

Applying the law to the instant facts, the references relied upon by the Office Action do not disclose or suggest the instant invention. Although Brooks-Walter *et al.*, Briles *et al.*, and Swialto *et al* may disclose a PspC protein or *pspA*-like nucleotides, no specific epitopic data or clades are presented. Further, none disclose or suggest the sequence of the *pspC* gene, PspC protein, or any part thereof. As Brooks-Walter *et al.*, Briles *et al.*, and Swialto *et al.* fail to teach or suggest the instantly claimed invention, they are not viable anticipatory documents.

Consequently, reconsideration and withdrawal of the Section 102 rejections are earnestly requested.

REQUEST FOR CORRECTED FILING RECEIPT

A Filing Receipt was issued May 12, 2000 with errors. It is respectfully requested that the records of the PTO be corrected, and that a corrected filing receipt be issued to show that this application is a continuation-in-part ("CIP") of U.S. application Serial No. 08/714,741, filed September 16, 1996, which is a CIP of U.S. application Serial No. 08/529,055, filed September 15, 1995, and that this application is also based upon and claims priority from U.S. Provisional application Serial No. 60/082,728, filed April 23, 1998. A new Declaration for Patent Application and Power of Attorney will be filed in due course.

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454312-3140**ADDITIONAL INFORMATION**

To assist the Examiner, mention is made of WO 97/0994, published from PCT/US96/14819, which corresponds to USSN 08/714,741, and claims priority from USSN 08/529,055; and, a copy of the allowed claims of USSN 08/714,741 are attached.


CONCLUSION

In view of the amendments, remarks and enclosures herewith, the application is in condition for allowance. Consideration and entry of this Amendment, favorable reconsideration of the application and prompt issuance of a Notice of Allowance are earnestly solicited.

The Commissioner is authorized to charge any deficiency or credit any overpayment to Deposit Account No. 50-0320.

Respectfully submitted,
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IN THE CLAIMS:

The following claims are amended as follows:

1. An isolated [and/]or purified polypeptide comprising at least one epitope or epitopic region of PspC.
3. The polypeptide of claim 1 [selected from the group]wherein the epitope or epitopic region is selected from the group consisting of: the alpha helical region of PspC, the proline region of PspC, the combination of the alpha helical and proline regions of PspC, the entire PspC molecule, amino acid(s) ([“aa”]) [of PspC clade A]1-590 of PspC clade A, aa 1-204 of PspC clade A, aa 46-204 of PspC clade A, aa 1-295 of PspC clade A, aa 46-295 of PspC clade A, aa 1-454 of PspC clade A, aa 46-454 of PspC clade A, aa 204-454 of PspC clade A, aa 295-454 of PspC clade A, aa 1-590 of PspC clade A, aa 46-590 of PspC clade A, aa 204-590 of PspC clade A, aa 295-590 of PspC clade A, aa 454-590 of PspC clade A, aa 1-652 of PspC clade A, aa 46-652 of PspC clade A, aa 204-652 of PspC clade A, aa 295-652 of PspC clade A, aa 454-652 of PspC clade A, aa 590-652 of PspC clade A, aa 1-892 of PspC clade A, aa 46-892 of PspC clade A, aa 204-892 of PspC clade A, aa 295-892 of PspC clade A, aa 454-892 of PspC clade A, aa 590-892 of PspC clade A, aa [of PspC clade B]1-664 of PspC clade B, aa 1-375 of PspC clade B, aa 1-445 of PspC clade B, aa 1-101 of PspC clade B, aa 1-193 of PspC clade B, aa 1-262 of PspC clade B, aa 1-355 of PspC clade B, aa 101-193 of PspC clade B, aa 101-262 of PspC clade B, aa 101-355 of PspC clade B, aa 101-375 of PspC clade B, aa 101-455 of PspC clade B, aa 193-262 of PspC clade B, aa 193-355 of PspC clade B, aa 193-375 of PspC clade B, aa 193-445 of PspC clade B, aa 262-355 of PspC clade B, aa 262-375 of PspC clade B, aa 262-445 of PspC clade B, aa 355-375 of PspC clade B, aa 355-445 of PspC clade B, aa 375-445 of PspC clade B, aa 101-664 of PspC clade B, aa 193-664 of PspC clade B, aa 262-664 of PspC clade B, aa 355-664 of PspC clade B, aa 375-664 of PspC clade B, aa 1-end of proline subregion A of PspC, aa 1-beginning of proline subregion B of PspC, aa 101-end of proline subregion A of PspC, aa 101-beginning of proline subregion B of PspC, aa 193-end of proline subregion A of PspC, aa 193-beginning of proline subregion B of PspC, aa 262-end of proline subregion A of PspC, aa 262-beginning of proline subregion B of PspC, aa 355-end of proline subregion A of PspC, aa 355-beginning of proline subregion B of PspC, aa 375-end of proline subregion A of PspC, or proline subregion A of PspC, aa 375-beginning of proline subregion B of PspC, proline

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subregion B of PspC, beginning of proline subregion B of PspC-aa 664 of PspC, aa 263-482 of PspC, aa 1-445 of PspC, and, aa 255-445 of PspC.

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IN THE SPECIFICATION:

Paragraph beginning at line 8 of page 1, is amended as follows:

This application is a continuation-in-part ("CIP") of U.S. application Serial No. 08/714,741, filed September 16, 1996 (allowed), which is a CIP of U.S. application Serial No. 08/529,055, filed September 15, 1995. This application is also based upon and claims priority from U.S. Provisional application Serial No. 60/082,728, filed April 23, 1998.

Paragraph beginning at line 10 of page 1, is amended as follows:

Reference also is made to: Briles et al., "Strain Selection of Pneumococcal Surface Proteins," U.S. application Serial No. 08/710,749, filed September 20, 1996, now U.S. Patent No. 5,955,089; [(allowed); Briles et al., "Pneumococcal Genes, Portions Thereof, Expression Products Therefrom, And Uses of Such Genes, Portions and Products," U.S. applications Serial Nos. 08/714,741, filed September 16, 1996, and 08/529,055, filed September 15, 1995, and]PCT applications PCT/US96/14819, filed September 16, 1996 and WO 97/09994, published March 20, 1997; Briles et al. "Oral Administration ...," U.S. application Serial Nos. 08/482,981, filed June 7, 1995, now U.S. Patent No. 6,232,116 [(allowed)]; U.S. application Serial No. 08/458,399, filed June 2, 1995, now U.S. Patent No. 6,231,870 and U.S. application Serial No. 08/657,751, filed May 30, 1996, now U.S. Patent No. 6,004,802 [(allowed)]; "Mucosal Administration ...," Briles et al., U.S. application Serial No. 08/446,201, filed May 19, 1995, now U.S. Patent No. 6,042,838 [(allowed;]filed as a CIP of USSN 08/246,636, filed May 20, 1994, now U.S. Patent No. 5,965,141 [(also allowed)]], and Briles et al., U.S. application Serial No. 08/312,949, filed September 30, 1994, now U.S. Patent No. 6,027,734 [(allowed); Briles et al., U.S. application Serial No. 08/319,795, filed May, 20, 1994 (allowed)]; Briles et al., "Epitopic Regions of Pneumococcal Surface Protein A," U.S. application Serial No. 08/319,795, filed May 20, 1994 now U.S. Patent No. 5,980,909; [U.S. application Serial No. 08/456,746, filed June 6, 1995 (now U.S. Patent No. 5,679,768; filed as a cont. USSN 08/048,896, filed April 20, 1993, now abandoned, which was as a CIP of USSN 07/835,698, filed February 12, 1992, now abandoned, which was as a CIP of USSN 07/656,773, now abandoned);] Briles et al., [""] "Structural Gene of Pneumococcal Protein", U.S. application Serial No. 08/467,852, filed

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June 6, 1995, [(now U.S. Patent No. 5,856,170[:]) (filed as a cont. of U.S. application Serial No. 08/247,491, filed May 23, 1994, now U.S. Patent No. 5,965,141), U.S. application Serial No. 08/072,070, filed June 3, 1993, [(now U.S. Patent No. 5,476,929,[]) and U.S. Patent Nos. 5,753,463 and 5,728,387 (from) U.S. application[s] Serial No[s]. 08/469,434, filed June 6, 1995, now U.S. Patent No. 5,753,463 and U.S. application Serial No. 214,164, filed March 14, 1994, now U.S. Patent No. 5,728,387[respectively]); Briles et al., "Truncated PspA ...," U.S. application Serial No. 08/214,222, filed March 17, 1994, [(now U.S. Patent No. 5,804,193[:]) and Briles et al. U.S. application Serial No. 08/468,985, now U.S. Patent No. 5,997,882 (allowed)]; Briles et al., "Immunoassay Comprising a Truncated Pneumococcal Surface Protein A (PspA)," U.S. application Serial No. 08/468,718, filed June 6, 1995, now U.S. Patent No. 5,871,943; U.S. application[s] Serial No[s]. 08/226,844, filed May 29, 1992;[,] U.S. applications Serial Nos. 08/093,907, filed July 5, 1994[.] and 07/889,918, filed July 5, 1994, both abandoned; PCT/US93/05191; and Briles et al., WO 92/1448.

Paragraph at page 28, line 25, is added as follows:

Deposit

E. coli containing a cloned PspC gene from *Streptococcus pneumoniae* strain EF6796, was deposited on July 24, 2001 with the American Type Culture Collection (ATCC), 12301 Parklawn Drive, Rockville, Maryland, 20852, USA, under accession number ATCC No. PTA-3526.